IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gerald Horn
Appl. No.:	09/854,414
Conf. No.:	7675
Filed:	May 10, 2001
Title:	OPHTHALMIC FORMULATIONS COMPRISING IMIDAZOLINE
Art Unit:	1614
Examiner:	Z. Fay
Docket No.:	114309-1007

Mail Stop Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING BY EXPRESS MAIL UNDER 37 CFR 1.10

Sir:

I hereby certify that the following documents relating to the above-identified application:

1. Transmittal Letter (duplicate);
2. Petition to the Withdraw Holding of Abandonment Based on Evidence that a Reply was Timely Mailed or Filed Pursuant to 37 C.F.R. § 1.181 (2 pgs.) including Exhibit A (1 pg.) and Exhibit B (19 pgs.).

are being deposited with the United States Postal Service with sufficient postage as Express Mail in an envelope addressed to:

Mail Stop Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on December 9, 2005.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

Heather Foster
Name of Person Mailing Correspondence

Signature

EV 551759111 US
Express Mail Mailing Label Number

TRANSMITTAL LETTER (General - Patent Pending)	Docket No. 114309-1007

In Re Application Of: **Gerald Horn**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/854,414	May 10, 2001	Z. Fay	24573	1614	7675

Title: **OPHTHALMIC FORMULATIONS COMPRISING IMIDAZOLINE**

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

Petition to the Withdraw Holding of Abandonment Based on Evidence that a Reply was Timely Mailed or Filed Pursuant to 37 C.F.R. § 1.181 (2 pgs.) including Exhibit A (1 pg.) and Exhibit B (19 pgs.); and return receipt postcard.

in the above identified application.

- ☒ No additional fee is required.
- ☐ A check in the amount of is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **02-1818** as described below.
  - ☐ Charge the amount of
  - ☒ Credit any overpayment.
  - ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Dated: **December 9, 2005**

Signature

Thomas C. Basso (46,541)
Cust. No. 24573

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

_____.
(Date)

Signature of Person Mailing Correspondence

Typed or Printed Name of Person Mailing Correspondence

cc:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gerald Horn
Appl. No.:	09/854,414
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Alexandria, VA 22313-1450

PETITION TO THE WITHDRAW HOLDING OF ABANDONMENT BASED ON EVIDENCE THAT A REPLY WAS TIMELY MAILED OR FILED PURSUANT TO 37 C.F.R. §1.181

Sir:

Applicant hereby submits this Petition to withdraw the holding of abandonment regarding the above-referenced patent application based on evidence that a reply was timely mailed or filed as discussed below in greater detail pursuant to 37 C.F.R., § 1.181.

On October 20, 2005, a Notice of Abandonment was mailed for alleged failure to timely file a proper reply to the non-final Office Action mailed on April 13, 2005 ("Office Action") regarding the above-referenced patent application. In response to the Office Action, Applicant mailed a RESPONSE TO OFFICE ACTION ("RESPONSE") on October 11, 2005 pursuant to the procedures detailed in 37 C.F.R. §1.8. Along with the RESPONSE, Applicant also submitted a petition for extension of time in addition to a Supplemental Information Disclosure Statement including PTO Form 1449 along with requisite transmittal forms. As *prima facie* evidence that the RESPONSE was timely filed, Applicant is submitting herewith a copy of the date stamped postcard indicating receipt of the RESPONSE and other associated filing papers by the United States Patent and Trademark Office.

Further, Applicant is submitting herewith as Exhibit B a copy of the RESPONSE in addition to the Petition for Extension of Time, Supplemental Information Disclosure, and the requisite transmittal forms that were submitted on October 11, 2005 along with the postcard

identifying same, a copy of which was date stamped by the Patent Office and provided herewith as Exhibit A as discussed above. Applicant notes that the copy of RESPONSE and other associated filing documents was retrieved from the Patent Application Information Retrieval ("PAIR") database of the United States Patent and Trademark Office, and further Applicant provides a copy of the Image File Wrapper section of the PAIR database that indicates receipt of the RESPONSE along with other associated filing papers by the Patent Office consistent with the enclosed date stamped postcard evidencing same.

Accordingly, Applicant respectively requests that this Petition be granted to withdraw the holding of abandonment for this case and that the present application be given early and favorable examination on the merits in view of same. If the Patent Office should have any further questions regarding this Petition, Applicant kindly requests that the Patent Office contact the undersigned attorney of record directly including by telephone in an attempt to bring a prompt resolution to any potential issues that may be raised.

Respectfully submitted,

BY _____

Thomas C. Basso (46,541)
Cust. No. 24573

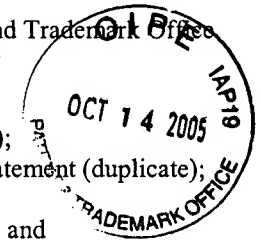
Dated: December 9, 2005

In re Patent Application of: Gerald Horn

OPHTHALMIC FORMULATIONS COMPRISING IMIDAZOLINE

Docket No.: 114309-1007; USSN: 09/854,414

On the date stamped hereon the U.S. Patent and Trademark Office hereby acknowledges receipt of the following:



1. Transmittal Letter (duplicate);
2. Petition for Extension of Time (duplicate);
3. Transmittal of Information Disclosure Statement (duplicate);
4. Response to Office Action (12 pgs.);
5. Suppl. Information Disclosure Statement; and
6. PTO Form 1449.

Mailed By US First Class Mail on: 10-11-2005 (TZB)

09/854,414 Ophthalmic formulations comprising an imidazoline

Application Data | Transaction History | Image File Wrapper | Continuity Data | Published Documents | Publication Dates | Address & Attorney/Agent

This application is officially maintained in electronic form. To View: Click the desired Document Description. To Download and Print: Check the desired document(s) and click StartDownload.

Mail Room Date	Document Description	Page Count	Select All / Start Download / Clear All
10-20-2005	Abandonment	2	☐
10-20-2005	Examiner Interview Summary Record (PTOL - 413)	2	☐
10-14-2005	Amendment - After Non-Final Rejection	1	☐
10-14-2005	Claims	8	☐
10-14-2005	Applicant Arguments or Remarks Made in an Amendment	3	☐
10-14-2005	Information Disclosure Statement (IDS) Filed	4	☐
10-14-2005	Extension of Time	1	☐
10-14-2005	Transmittal to TC	1	☐
04-13-2005	Non-Final Rejection	6	☐
04-13-2005	List of References cited by applicant and considered by examiner	2	☐
04-13-2005	Index of Claims	1	☐
04-13-2005	Search information including classification, databases and other search related notes	1	☐
08-24-2004	Information Disclosure Statement (IDS) Filed	6	☐
08-24-2004	NPL Documents	8	☐
01-15-2004	Terminal Disclaimer Filed	2	☐
01-15-2004	Information Disclosure Statement (IDS) Filed	3	☐
12-22-2003	Amendment - After Non-Final Rejection	1	☐
12-22-2003	Claims	8	☐
12-22-2003	Applicant Arguments or Remarks Made in an Amendment	2	☐
12-22-2003	Extension of Time	3	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Appl. No.:	09/854,414
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Sir:

In response to the Office Action dated April 13, 2005, Applicant submits as follows:

A listing of claims begins on page 2 of this paper.

Remarks begin on page 10 of this paper.

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-9 (canceled)

Claim 10 (previously presented): A method of modulating pupil dilation, comprising:

administering to an eye of a patient a formulation comprising a first compound including an alpha 1 antagonist capable of disrupting an endogenous compound which stimulates a dilator muscle of the eye and a second compound characterized by its ability to reduce eye redness; and

allowing the formulation to remain in contact with the eye for a period of time and under lighting conditions where the dilator muscles would be stimulated in the absence of the formulation;

wherein the formulation as administered to a human eye elicits a redness response rating of +1 or less.

Claim 11 (previously presented): The method of claim 10, wherein the first compound is selected from the group consisting of an imidazoline, an alkylating agent including phenoxybenzamine, a benzenesulfonamide including Tamsulosin, a piperazinyl quinazoline including prazosin and not including dapiprazole.

Claim 12 (canceled)

Claim 13 (previously presented): The method of claim 10, wherein the second compound characterized by its ability to reduce eye redness is tetrahydrozoline.

Claim 14 (previously presented): The method of claim 10, wherein the formulation is administered in an amount so as to optimize pupil diameter in dim light to no more than 6 mm and pupil diameter in bright light to no less than 1 mm.

Claim 15 (original): The method according to claim 14, wherein said optimized pupil diameter in dim light is between and including 3 mm and 5 mm.

Claims 16-17 (canceled)

Claim 18 (original): A method for optimizing pupil diameter in dim light by minimizing its dilatation in response to less light, comprising administering a therapeutically effective amount of an imidazoline to an eye of a person in need thereof.

Claim 19 (original): The method according to claim 18, wherein said dilatation of the pupil diameter in dim light is minimized in response to less light, and wherein said method does not induce ciliary muscle contraction.

Claim 20 (original): The method of claim 19, wherein the imidazoline is selected from the group consisting of Phentolamine and Tolamine.

Claim 21 (original): The method of claim 19, wherein the imidazoline is phentolamine.

Claim 22 (original): The method of claim 21, further comprising: administering tetrahydrozoline hcl.

Claim 23 (currently amended): A method of modulating pupil dilation, comprising:

administering to an eye of a patient a formulation comprising a compound including an alpha 1 antagonist capable of disrupting endogenous compounds which stimulate dilator muscles of the eye and eliciting a redness response of about +1 or less on a scale of from 0 to +4; and

allowing the formulation to remain in contact with the eye for a period of time and under lighting conditions where the dilator muscles would be stimulated in the absence of the formulation.

Claim 24 (original): The method of claim 23, wherein the compound is selected from the group consisting of an imidazoline, an alkylating agent including phenoxybenzamine, a

benzenesulfonamide including Tamsulosin, a piperazinyl quinazoline including prazosin and not including dapiprazole.

Claim 25 (original): The method of claim 23, wherein the formulation further comprises a compound characterized by its ability to reduce eye redness.

Claim 26 (previously presented): The method of claim 25, wherein the compound characterized by its ability to reduce eye redness is tetrahydrozoline.

Claim 27 (previously presented): The method of claim 23, wherein the formulation is administered in an amount so as to optimize pupil diameter in dim light to no more than 6 mm and pupil diameter in bright light to no less than 1 mm.

Claim 28 (original): The method according to claim 27, wherein the optimized pupil diameter in dim light ranges from about 3 mm to about 5 mm.

Claims 29-36 (canceled)

Claim 37 (previously presented): An ophthalmic, night vision formulation, comprising:

a sterile aqueous carrier;

a therapeutically effective amount of a first pharmaceutically active compound including an alpha 1 antagonist capable of disrupting endogenous compounds which stimulate dilator muscles of a human eye; and

a second pharmaceutically active compound characterized by its ability to reduce redness in a human eye.

Claim 38 (previously presented): The ophthalmic formulation of claim 37, wherein the second active compound is tetrahydrozoline.

Claim 39 (original): The formulation of claim 37, wherein the first active compound is selected from the group consisting of an imidazoline including phentolamine and tolamine, an

alkylating agent including phenoxybenzamine, a benzenesulfonamide including Tamsulosin, a piperazinyl quinazoline including prazosin and not including dapiprazole.

Claim 40 (original): The formulation of claim 37, wherein the first active compound is an imidazoline present in a concentration in a range of from about 0.01 milligrams per cubic centimeter of aqueous carrier to about 50 milligrams per cubic centimeter of aqueous carrier and wherein the solvent comprises an ophthalmic artificial tear solution.

Claims 41-42 (canceled)

Claim 43 (previously presented): A method of reducing adverse visual effects of spherical aberrations on a human eye, comprising:

administering to a human eye a first active compound including an alpha 1 antagonist capable of reducing dilation of a human eye exposed to a low light environment as compared to dilation which naturally occurs absent the compound and generating a redness response of about +1 or less on a scale of 0 to +4.

Claim 44 (previously presented): An ophthalmic formulation, comprising: a first active compound comprising an imidazoline, the first active compound capable of reducing dilation of a human eye exposed to a low light environment as compared to dilation which naturally occurs absent the compound and generating a redness response of about +1 or less on a scale of 0 to +4, and a second active compound capable of reducing eye redness in a human eye.

Claim 45 (previously presented): The formulation of claim 44, wherein the imidazoline is selected from the group consisting of phentolamine and tolamine.

Claim 46 (previously presented): The formulation of claim 44, wherein the first active compound is composed of phentolamine.

Claim 47 (previously presented): The formulation of claim 44, wherein the second active compound comprises tetrahydrozoline.

Claim 48 (previously presented): The formulation of claim 47, wherein the second active compound comprises tetrahydrozoline hcl.

Claim 49 (previously presented): The formulation of claim 48, further comprising an aqueous solvent.

Claim 50 (previously presented): The formulation of claim 49, wherein the aqueous solvent comprises an artificial tear solution.

Claim 51 (previously presented): An ophthalmic, night vision formulation, comprising:

a sterile aqueous carrier;

a therapeutically effective amount of a first pharmaceutically active compound comprising an imidazoline, the first pharmaceutically active compound capable of disrupting endogenous compounds which stimulate dilator muscles of a human eye; and

a second pharmaceutically active compound capable of reducing redness in a human eye.

Claim 52 (previously presented): The ophthalmic formulation of claim 51, wherein the second active compound is tetrahydrozoline.

Claim 53 (previously presented): The formulation of claim 51, wherein the imidazoline is selected from the group consisting of phentolamine and tolamine.

Claim 54 (previously presented): The formulation of claim 53, wherein the imidazoline is present in a concentration in a range of from about 0.01 milligrams per cubic centimeter of aqueous carrier to about 50 milligrams per cubic centimeter of aqueous carrier and wherein the sterile aqueous carrier comprises an ophthalmic artificial tear solution.

Claim 55 (previously presented): A method of reducing adverse visual effects of spherical aberrations on a human eye, comprising:

administering to a human eye a first active compound comprising imidazoline, the first active compound capable of reducing dilation of a human eye exposed to a low light

environment as compared to dilation which naturally occurs absent the compound and generating a redness response of about +1 or less on a scale of 0 to +4.

Claim 56 (previously presented): The method of claim 55 wherein the imidazoline is selected from the group consisting of phentolamine and tolamine.

Claim 57 (previously presented): An ophthalmic formulation, comprising: a first active compound comprising an alpha 1 antagonist not including a dapiprazole, the first active compound capable of reducing dilation of a human eye exposed to a low light environment as compared to dilation which naturally occurs absent the compound and generating a redness response of about +1 or less on a scale of 0 to +4, and a second active compound capable of reducing eye redness in a human eye.

Claim 58 (previously presented): The formulation of claim 57, wherein the second active compound comprises tetrahydrozoline.

Claim 59 (previously presented): The formulation of claim 57, wherein the second active compound comprises tetrahydrozoline hcl.

Claim 60 (previously presented): The formulation of claim 57, further comprising an aqueous solvent.

Claim 61 (previously presented): The formulation of claim 60, wherein the aqueous solvent comprises an artificial tear solution.

Claim 62 (previously presented): A method of modulating pupil dilation, comprising:

administering to an eye of a patient a formulation comprising a first compound comprising an alpha 1 antagonist not including a dapiprazole, and a second compound capable of reducing eye redness, the first compound capable of disrupting an endogenous compound which stimulates a dilator muscle of the eye; and

allowing the formulation to remain in contact with the eye for a period of time and under lighting conditions where the dilator muscles would be stimulated in the absence of the formulation,

wherein the formulation as administered to a human eye elicits a redness response rating of +1 or less.

Claim 63 (previously presented): The method of claim 62, wherein the second compound comprises tetrahydrozoline.

Claim 64 (previously presented): The method of claim 62, wherein the formulation is administered in an amount so as to optimize pupil diameter in dim light to no more than 6 mm and pupil diameter in bright light to no less than 2 mm.

Claim 65 (previously presented): The method according to claim 62, wherein the optimized pupil diameter in dim light ranges from about 3 mm to 5 mm.

Claim 66 (previously presented): An ophthalmic, night vision formulation, comprising:

a sterile aqueous carrier; and

a therapeutically effective amount of a pharmaceutically active compound including an alpha 1 antagonist capable of disrupting endogenous compounds which stimulate dilator muscles of a human eye and generating a redness response of about +1 or less on a scale of 0 to +4.

Claim 67 (previously presented): The formulation of claim 66, wherein the pharmaceutically active compound is selected from the group consisting of an imidazoline, an alkylating agent including phenoxybenzamine, a benzenesulfonamide including Tamsulosin, a piperazinyl quinazoline including prazosin and not including dapiprazole.

Claim 68 (original): The formulation of claim 66, wherein the imidazoline is selected from the group consisting of phentolamine and tolamine.

Claim 69 (original): The formulation of claim 66, wherein the pharmaceutically active compound is an imidazoline present in a concentration in a range of from about 0.01 milligrams per cubic centimeter of aqueous carrier to about 50 milligrams per cubic centimeter of aqueous carrier and wherein the solvent comprises an ophthalmic artificial tear solution.

REMARKS

In the Office Action, claims 10, 11, 13-15, 18-25, 37-40, and 43-69 are rejected under 35 U.S.C. §112, first paragraph. Applicant believes that this rejection should be withdrawn at least based on the reasons set forth below.

More specifically, the Patent Office alleges that claims 10, 11, 13-15, 18-25, 37-40, and 43-69 are not enabling pursuant to §112, first paragraph. Applicant believes that the specification provides sufficient support such that one skilled in the art can practice the subject matter as presently claimed without undue experimentation.

Of the pending claims at issue, claims 10, 18, 23, 37, 43, 44, 51, 55, 57, 62, and 66 are the sole independent claims. Claims 10 recites a method of modulating pupil dilation; claim 18 recites a method for optimizing pupil diameter in dim light; claim 23 recites a method of modulating pupil dilation; claim 37 recites an ophthalmic, night vision formulation; claim 43 recites a method of reducing adverse visual effects of spherical aberrations on a human eye; claim 44 recites an ophthalmic formulation; claim 51 recites an ophthalmic, night vision formulation; claim 55 recites a method of reducing adverse visual effects of spherical aberrations on a human eye; claim 57 recites an ophthalmic formulation; claim 62 recites a method of modulating pupil dilation; and claim 66 recites an ophthalmic, night vision formulation. Each of the independent claims recite, in part, alpha 1 antagonist compounds that are capable of disrupting endogenous compounds which simulate dilator muscles of the eye, such as an imidazoline and an alkylating agent.

As further supported in the specification on page 13, the claimed invention utilizes a specific class of compounds known as alpha 1 antagonists to inhibit pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accommodation. Ophthalmic formulations that include such class of alpha 1 antagonist compounds can allow improvement in quality of vision in dim light without negative clinical effects in normal lighting conditions. See, Specification, page 13, paragraph 47. Examples of alpha 1 antagonists include an imidazoline, such as phentolamine, and an alkylating agent, such as phenoxybenzamine, as further supported in the Specification, for example, on page 25 at paragraph 85.

Further, Applicant has conducted experiments that demonstrate the beneficial effects of the claimed invention. For example, Table 1 on page 27 of the specification demonstrates that four different types of alpha 1 antagonist compounds can reduce pupil diameter in darkness in increased amounts as compared to dapiprazole. In this regard, a phentolamine-based solution reduced the pupil diameter by 3.5 mm; a phenoxybenzamine-based solution reduced the pupil diameter by 2.0 mm; a prazosin-based solution reduced the pupil diameter by 1.5 mm; and a tolamine-based solution reduced the pupil diameter by 1.5 mm. See, Specification, Table 1. In Example 2, six additional specific types of alpha 1 antagonist compounds (e.g. tamsulosin, bunazosin, alfuzonsin, urapidil, ketanserin, and indoramin) are indicated to have some clinical effectiveness as well. See, Specification, page 25, paragraph 85.

Further, Applicant conducted an additional test to demonstrate the beneficial effects on vision by reducing the pupil diameter in dim light. As shown in Table 2, the glare and halo effects were reduced in addition to an improvement in depth perception by reducing the pupil diameter in dim light. See, Specification, page 28.

The Patent Office appeared to rely on page 4 of the specification in support of their position as indicated on pages 2-3 of the Office Action. Contrary to this position, Applicant believes that the specification in this part provides further guidance to one skilled in the art, thus facilitating the practice of the claimed invention. With respect to reference of the indols, the specification provides that the alpha-2 activity as represented by indols is of no clinical benefit. As previously discussed, Applicant has discovered that compositions that display alpha-1 antagonist activity can improve quality of vision in dim light without negative clinical effect in normal lighting conditions. This is consistent with the testing that was conducted by Applicant and as illustrated, for example, in Table 1 on page 27 where the compound yohimbe having alpha-2 activity displayed no effect on pupil diameter reduction in dim light. Thus, this provides further guidance to one skilled in the art that the alpha 1 antagonist activity is most predominant with respect to reducing pupil size in dim light, and thus improving quality of vision.

With respect to specific types of alpha 1 antagonist compounds, such as an alkylating agent, these types of compounds may have less of an effect on pupil size as compared to, other types of alpha 1 compounds, such as an imidazoline, and further may cause greater redness. See, specification, for example, Table 1, page 27. Again, this should provide further guidance to one skilled in the art that one type of alpha 1 antagonist may be more preferred in formulation than another and also may require an additional compound to reduce eye redness. Clearly, this added

description provides the skilled artisan with a greater frame work and understanding of the claimed invention, and thus facilitates the practice of same. Again, Applicant has indicated that at least 10 specific types of compounds having alpha 1 antagonist properties can display clinical effectiveness with respect to pupil diameter reduction in darkness (see, Specification, Table 1 and Example 2 at pages 24 and 25) and further that reduced pupil size does indeed have a beneficial effect on vision in dim light (see, Specification, Table 2 at page 28) as previously discussed.

Based on at least these reasons, Applicant believes that the specification provides sufficient support and guidance such that one skilled in the art can readily practice the claimed invention with undue experimentation. Therefore, Applicant believes that pending claims 10, 11, 13-15, 18-25, 37-40, and 45-69 satisfy the enablement requirement pursuant to 35 U.S.C. § 112, first paragraph. To the extent that claims 26 and 27 are rejected for alleged §112 reasons, Applicant believes that claims 26 and 27 should satisfy the requirements of 35 U.S.C. §112, paragraph 1 for substantially the same reasons as discussed above.

Accordingly, Applicant respectively requests that this rejection be withdrawn.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

BY _____
Thomas C. Basso (46,541)
Customer No. 29175

Date: October 11, 2005

OCT 14 2005
PATENT & TRADEMARK OFFICE

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
114309-1007

In Re Application: **Gerald Horn**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/854,414	May 10, 2001	Z. Fay	24573	1614	7675

Title: **OPHTHALMIC FORMULATIONS COMPRISING IMIDAZOLINE**

Payment of Fee
(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

☐ A check in the amount of is attached.

☒ The Director is hereby authorized to charge and credit Deposit Account No. **02-1818** as described below.

- ☒ Charge the amount of **$180.00**
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.

☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Certificate of Transmission by Facsimile*

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No.

_____
(Date)

Signature

Typed or Printed Name of Person Signing Certificate

Certificate of Mailing by First Class Mail

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

October 11, 2005
(Date)

Signature of Person Mailing Correspondence

Heather Foster

Typed or Printed Name of Person Mailing Certificate

*This certificate may only be used if paying by deposit account.

Signature

Dated: **October 11, 2005**

Thomas C. Basso (46,541)
Cust. No. 29175

cc:

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c))	Docket No. 114309-1007

OCT 14 2005 PATENT & TRADEMARK OFFICE

In Re Application Of: **Gerald Horn**

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Title: **OPHTHALMIC FORMULATIONS COMPRISING IMIDAZOLINE**

Address to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

37 CFR 1.97(b)

1. ☐ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

2. ☒ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

   ☐ the statement specified in 37 CFR 1.97(e);

   OR

   ☒ the fee set forth in 37 CFR 1.17(p).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gerald Horn
Appl. No.:	09/854,414
Conf. No.:	7675
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Art Unit:	1614
Examiner:	Z. Fay
Docket No.:	114309-1007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 37 C.F.R. 1.97, and 37 C.F.R. 1.98, Applicants request that a citation and examination of the references cited below, and on the attached PTO-1449 form be made during the course of examination of the above-identified application for United States patent. Pursuant to 37 C.F.R. 1.98, copies of all foreign patent documents and non-patent documents are enclosed.

U.S. PATENT DOCUMENTS

Document No.	Date	Inventor
6,730,691	May 4, 2004	Galin

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____
Thomas C. Basso (46,541)
Cust. No. 29175

Dated: October 11, 2005

INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary) PTO Form 1449	Atty Docket No. 114309-1007	Application No. 09/854,414
	Applicant: Gerald Horn	
	Filing Date: May 10, 2001	Group: 7675

U.S. PATENT DOCUMENTS

Examiner's Initials		Document Number	Publication Date	Inventor	Class	Subclass	Filing Date If Appropriate
		6,730,691	May 4, 2004	Galin			

FOREIGN PATENT DOCUMENTS

Examiner's Initials		Document Number	Publication Date	Country	Class	Subclass	Translation Yes	Translation No

Examiner's Initials		**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*

Examiner:	Date Considered:
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) (Small Entity)	Docket No. 114309-1007

OCT 14 2005 PATENT & TRADEMARK OFFICE

In Re Application Of: Gerald Horn

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/854,414	May 10, 2001	Z. Fay	24573	1614	7675

Invention: **OPHTHALMIC FORMULATIONS COMPRISING IMIDAZOLINE**

COMMISSIONER FOR PATENTS:

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a response to the Office Action of April 13, 2005 (Date) in the above-identified application.

The requested extension is as follows (check time period desired):

☐ One month ☐ Two months ☒ Three months ☐ Four months ☐ Five months

from: July 13, 2005 (Date) until: October 13, 2005 (Date)

☐ Applicant claims small entity status. See 37 CFR 1.27

The fee for the extension of time is $510 and is to be paid as follows:

☐ A check in the amount of the fee is enclosed.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. 02-1818

☒ If an additional extension of time is required, please consider this a petition therefor and charge any additional fees which may be required to Deposit Account No. 02-1818

☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Dated: October 11, 2005

Signature

Thomas C. Basso (46,541)
Cust. No. 29175

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on October 11, 2005 (Date)

Signature of Person Mailing Correspondence

Heather Foster

Typed or Printed Name of Person Mailing Correspondence

10/17/2005 YPOLITE1 00000048 021818 09854414

01 FC:2253 510.00 DA

cc:

P12SMALUREV08

TRANSMITTAL LETTER
(General - Patent Pending)

Docket No.
114309-1007

In Re Application Of: **Gerald Horn**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/854,414	May 10, 2001	Z. Fay	24573	1614	7675

Title: **OPHTHALMIC FORMULATIONS COMPRISING IMIDAZOLINE**

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

Petition for Extension of Time (duplicate); Transmittal of Information Disclosure Statement (duplicate); Respone to Office Action (12 pgs.);Supplemental Information Disclosure Statement; PTO Form 1449; and return receipt postcard.

in the above identified application.

- ☒ No additional fee is required.
- ☐ A check in the amount of is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. 02-1818 as described below.
  - ☐ Charge the amount of
  - ☒ Credit any overpayment.
  - ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

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